

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant :	Alan Wellington Faull et al.	Art Unit :	1626
Patent No. :	7,572,826	Examiner :	Janet L. Coppins
Issue Date :	August 11, 2009	Conf. No. :	7821
Serial No. :	10/542,326		
Filed :	July 13, 2005		
Title :	THIOPHENE-CARBOXAMIDE DERIVATIVES AND THEIR USE AS INHIBITORS OF THE ENZYME IKK-2		

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)**

Patentees hereby request reconsideration of the Patent Term Adjustment (PTA) accorded the above-referenced patent. Reconsideration of the final PTA calculation to increase total PTA from 112 to 173 days, is respectfully requested.

**REMARKS**

(1) Measuring Overlap of “A Delay” and “B Delay”

“A Delays” are defined as delays by the U.S. Patent and Trademark Office (PTO) under 35 U.S.C. § 154(b)(1)(A), which guarantees prompt PTO response. “B Delays” are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than three year application pendency. To the extent that the periods of delay overlap, the period of any term adjustment shall not exceed the actual number of days the issuance of the patent was delayed. 35 U.S.C. § 154(b)(2)(A). As outlined in Wyeth et al. v. Jon W. Dudas (580 F. Supp. 2d 138; 88 USPQ 2d 1538), the only way that these periods of time can “overlap” is if they occur on the same day. If an “A delay” occurs on one calendar day and a “B delay” occurs on another calendar day, they do not overlap and 35 U.S.C. § 154(b)(2)(A) does not limit the extension to one day. Id.

The PTA for the instant patent, as currently calculated and shown on the face of the patent, apparently relies on the premise that the application was delayed under

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35 U.S.C. § 154(b)(1)(B) *before* the initial three-year period expired. The Wyeth v. Dudas court determined that this construction cannot be squared with the language of

35 U.S.C. § 154(b)(1)(B), which applies “if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years.”

“B delay” begins only after the PTO has failed to issue a patent within three years, not before.

Id.

(2) Measuring “B Delay” for a National Stage Filing under 35 U.S.C. § 371

In addition to and independent of the “overlap” issue addressed above, Patentees respectfully submit that the Office did not apply the proper standard for determining the period of “B Delay” under 35 U.S.C. § 154(b)(1)(B). It is Patentees’ understanding that for purposes of calculating “B Delay,” the Office measured application pendency as beginning on July 13, 2005, the date on which the application fulfilled the requirements of 35 U.S.C. § 371.

The term of a patent shall, under certain circumstances, be extended if the Office fails to issue a patent within three years after the “actual filing date” of the application.

**(B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION**

**PENDENCY.**- Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States ... the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

35 U.S.C. § 154(b)(1)(B). (emphasis added)

37 C.F.R. § 1.702(b) explains the meaning of the term “actual filing date” as used in 35 U.S.C. § 154(b)(1)(B). As detailed below, PTO delay for a national stage application begins if the Office fails to issue a patent within three years after the date the national stage “commenced under 35 U.S.C. 371(b) or (f).”<sup>1</sup>

(b) *Failure to issue a patent within three years of the actual filing date of the application.* Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was

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<sup>1</sup> Consistent with 37 C.F.R. § 1.702(b), MPEP § 2730 states that “[i]n the case of an international application, the phrase ‘actual filing date of the application in the United States’ [as used in 35 U.S.C. § 154(b)(1)(B)] means the date the national stage commenced under 35 U.S.C. 371(b) or (f).”

Applicant : Alan Wellington Faull et al.  
Patent No. : 7,572,826  
Issued : August 11, 2009  
Serial No. : 10/542,326  
Filed : July 13, 2005  
Page : 3 of 6

Attorney's Docket No.: 06275-0461US1 / 100929-1P US

delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application, but not including... 37 C.F.R. § 1.702(b). (emphasis added)

35 U.S.C. §§ 371(b) and (f) refer to the time when a national stage application “commences.”

(b) Subject to subsection (f) of this section, the national stage shall commence with the expiration of the applicable time limit under article 22 (1) or (2), or under article 39 (1)(a) of the treaty. 35 U.S.C. § 371(b). (emphasis added)

(f) At the express request of the applicant, the national stage of processing may be commenced at any time at which the application is in order for such purpose and the applicable requirements of subsection (c) of this section have been complied with. 35 U.S.C. § 371(f).

35 U.S.C. § 371(f) relates to the situation where an applicant files an express request for early processing of an international application. In the absence of filing such a request, the U.S. national stage commences under the provisions of 35 U.S.C. § 371(b), i.e., with the expiration of the applicable time limit under article 22(1) or (2), or under article 39(1)(a) of the treaty. The term “the treaty” refers to “the Patent Cooperation Treaty done at Washington, on June 19, 1970.” See 35 U.S.C. § 351(a).

#### REVIEW OF PATENT TERM ADJUSTMENT CALCULATION

##### “A Delay”

A first PTO action was due on or before September 13, 2006 (the date that is fourteen months after July 13, 2005, the date on which the application was filed). The PTO mailed the first non-final Office Action on April 5, 2007, thereby according a PTO Delay of 204 days. Patentees do not dispute the PTO’s calculation for this “A Delay” from September 14, 2006 (the day after the date that is fourteen months after the date on which the application was filed), to April 5, 2007. See 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1).

A PTO action was due on or before June 11, 2008 (the date that is four months after February 11, 2008, the date on which a response to Office Action was filed). The PTO mailed a non-final Office Action on June 13, 2008, thereby according a PTO Delay of 2 days. Patentees

do not dispute the PTO's calculation for this "A Delay" from June 12, 2008 (the day after the date that is four months after the date on which a response to Office Action was filed), to June 13, 2008. See 37 C.F.R. §§ 1.702(a)(2) and 1.703(a)(2).

In view of the periods of "A Delay" detailed above, the total "A Delay" for this patent should be calculated as 206 days.

#### "B Delay"

The present application is a national stage filing under 35 U.S.C. § 371 of international application number PCT/GB2004/000096, filed January 13, 2004, which claims the benefit of priority of Sweden application number 0300092-4, filed January 15, 2003.

The national stage for the present application "commenced" under the provisions of 35 U.S.C. § 371(f), i.e., upon express request for processing of the application and upon compliance with all the applicable requirements of 35 U.S.C. § 371(c).<sup>2</sup> As a result, the date that the national stage commenced was July 13, 2005.

The period beginning on July 14, 2008 (the day after the date that is three years after July 13, 2005, the date on which the national stage commenced), and ending August 11, 2009 (the date the patent was issued), is 394 days in length.

"B Delay" may not include the number of days in the period beginning on the date on which a Request for Continued Examination was filed and ending on the date the patent was issued. In the present application, a Request for Continued Examination was filed on September 12, 2008, and the patent issued on August 11, 2009, resulting in a period of 333 days that must be excluded from the three year delay calculation. See 37 C.F.R. §§ 1.702(b)(1) and 1.703(b)(1).

In addition, "B Delay" may not include the number of days in the period beginning on the date on which a Notice of Appeal was filed and ending on the date of mailing of a Notice of Allowance. In the present application, no Notice of Appeal was filed. See 37 C.F.R. §§ 1.702(b)(4) and 1.703(b)(4).

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<sup>2</sup> A complete request for early processing under 35 U.S.C. § 371(f) was filed with the present application.

Applicant : Alan Wellington Faull et al.  
Patent No. : 7,572,826  
Issued : August 11, 2009  
Serial No. : 10/542,326  
Filed : July 13, 2005  
Page : 5 of 6

Attorney's Docket No.: 06275-0461US1 / 100929-1P US

In view of the periods of "B Delay" detailed above, the total "B Delay" for this patent should be calculated as 61 days (i.e., 394 days minus 333 days). The PTO calculated 0 days of delay for issuance of a patent more than three years after filing. Patentees respectfully submit that the PTO's calculation of this "B Delay" is incorrect and that the correct PTO Delay for issuance beyond three years from filing is 61 days. See 37 C.F.R. §§ 1.702(b) and 1.703(b).

#### Overlap of "A Delay" and "B Delay"

As detailed above, "A Delay" accumulated during the following periods:

September 14, 2006, to April 5, 2007; and

June 12, 2008, to June 13, 2008.

As detailed above, "B Delay" accumulated during the following period:

July 14, 2008, to September 12, 2008.

As such, the periods of "A Delay" and "B Delay" do not overlap (i.e., occur on the same calendar day).

#### Applicant Delay

A reply to an Office Action was due on or before November 9, 2007 (the date that is three months after August 9, 2007, the date on which the Office Action was mailed). Patentees filed a response to the Office Action on February 11, 2008, thereby according an Applicant Delay of 94 days. Patentees do not dispute the PTO's calculation for this Applicant Delay from November 10, 2007 (the day after the date that is three months after the date on which the Office Action was mailed), to February 11, 2008. See 37 C.F.R. § 1.704(b).

In view of the period of Applicant Delay detailed above, the total Applicant Delay for this patent should be calculated as 94 days.

#### Terminal Disclaimer

This patent is not subject to a terminal disclaimer.

Applicant : Alan Wellington Faull et al.  
Patent No. : 7,572,826  
Issued : August 11, 2009  
Serial No. : 10/542,326  
Filed : July 13, 2005  
Page : 6 of 6

Attorney's Docket No.: 06275-0461US1 / 100929-1P US

### Conclusion

In consideration of the events described above, Patentees believe the PTA calculation of 112 days is incorrect. As such, Patentees respectfully request reconsideration of the PTA in the following manner:

- 1) Total PTO Delay should be calculated as 267 days (i.e., the sum of 206 days of "A Delay" and 61 days of "B Delay");
- 2) Total Applicant Delay should be calculated as 94 days; and
- 3) Total PTA should be calculated as 173 days.

The fee of \$200 required under 37 C.F.R. § 1.18(e) is being submitted herewith. Please apply any other required charges or credits to Deposit Account No. 06-1050, referencing attorney docket number 06275-0461US1.

Respectfully submitted,

Date: October 9, 2009

/Teresa A. Lavoie/  
Teresa A. Lavoie, Ph.D.  
Reg. No. 42,782

Fish & Richardson P.C.  
PTO Customer No. 26164  
Telephone: (612) 335-5070  
Facsimile: (877) 769-7945